Antibiotic	Content per disc
Bacitracin	0.04 unit.
Nystatin	100 units.

(b) Packaged in a container bearing on its label or labeling the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark.

(ii) The potency of each disc in the batch.

(iii) The expiration date as prescribed under § 432.5(a)(3) of this chapter.

(iv) The statement: Not for Susceptibility Testing.

(2) On the labeling within or attached to the package: Adequate directions for use.

§ 433.21 Antibiotics for diagnostic use.

Antibiotics packaged for the withdrawal of individually weighed portions and intended for use solely in laboratory procedures in connection with the diagnosis or treatment of disease and conspicuously so labeled shall be exempt from the certification requirements of section 502(l) and 507 of the act and the certification requirements of section 512(n) of the act if they comply with all the following conditions:

(a) The potency, moisture content, and identity comply with the standards prescribed for the antibiotic by the specific regulations issued in this chapter.

(b) It is packaged in immediate containers that are tight containers as defined by the U.S.P. Each such container shall contain not more than 1 gram.

(c) Each package bears on the label or labeling of its outside wrapper or container and the immediate container the following:

(1) The statements ''For the withdrawal of individual portions of antibiotic. Each portion must be weighed before use. Diagnostic reagent. For professional use only.''

(2) The number of milligrams or grams contained in each immediate container and the potency per milligram.

(3) The batch mark.

(4) The statement ''Expiration date _____'', the blank being filled in with the date that does not exceed the expiration date authorized for the antibiotic by this chapter.

(d) The circular or other labeling within or attached to the package bears directions adequate for the use of such drug.

CROSS REFERENCES: For tests and methods of assay and certification of antibiotics susceptibility discs for laboratory diagnosis of disease, see §§ 460.1 and 460.6 of this chapter.

§ 433.22 Biologic drugs that contain antibiotics as a preservative.

Biological drugs that contain any certifiable antibiotic drug subject to the regulations in this chapter, and the purpose of the antibiotic is for use only as a preservative and the biological drug is conspicuously so labeled, shall be exempt from the requirements of sections 502(l) and 507 of the act and the certification requirements of section 512(n) of the act, if such drugs are licensed under the Public Health Service Act of July 1, 1944 (58 Stat. 682; 42 U.S.C. 201 et seq.) or under the Virus-Serum-Toxin Act of March 4, 1913 (37 Stat. 832; 21 U.S.C. 151 et seq.).

§ 433.23 Microbiological culture media containing antibiotics.

Microbiological culture media that contain any certifiable antibiotic drug subject to the regulations in this chapter shall be exempt from the requirements of sections 502(l) and 507 of the act and the certification requirements of section 512(n) of the act if:

(a) They are intended for use in tissue culture and the antibiotic drug is added solely for use as an aid in the prevention of microbial contamination; or

(b) They are intended for use in the isolation of selected organisms from mixed cultures and the antibiotic drug is added solely for use as an aid in such isolation; and

(c) The certifiable antibiotic drug used in such culture media complies with the applicable standards of identity, strength, quality, and purity prescribed therefor.

§ 433.24 Exemption of antibiotic drugs for use in teaching, law enforcement, research, and analysis.

Antibiotic drugs subject to section 507 or 512(n) of the act shall be exempt